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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	**PAPER NUMBER**
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,137	MARWICK ET AL.	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ :
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The Information Disclosure Statement filed on is acknowledged. The Information Disclosure Statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Sunagawa et al. (US Patent No. 6,770,034).

Sunagawa et al. disclose an apparatus for determining vascular characteristics for early detection of cardiovascular disease, comprising: an ultrasonic signal source (1) for directing ultrasound signals at an artery (column 5, lines 50-59); an ultrasonic signal receiver (1) for receiving ultrasound signals reflected from or transmitted through the artery (column 5, lines 50-59, referring to ultrasonic probe receiving a resulting ultrasonic reflected wave from a tissue); and a processor (i.e. data analysis

section/means (8) which is a device that can perform operations on data, such as calculating the movement velocity and displacement of the target living body tissue from the ultrasound signals) coupled to the ultrasonic signal receiver for: analyzing signals received by the ultrasonic signal receiver to extract arterial displacement data (column 6, lines 49-53; column 12, lines 30-60); adjusting said arterial displacement data using blood pressure data (column 12, lines 30-35; column 13, lines 33-55); and analyzing adjusted arterial displacement data to characterize vascular function (column 13, lines 14-23). See Figure 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al. (US Patent No. 6,770,034) in view of Lin (US Patent No. 5,910,119).

With regards to claims 1 and 6, Sunagawa et al. disclose an apparatus and method for determining vascular characteristics for early detection of cardiovascular disease (column 2, lines 22-31) including the steps of: i) acquiring velocity displacement data using an ultrasonic signal source (1) directing ultrasound signals at an artery and an ultrasonic signal receiver (1) receiving ultrasound signals reflected from or transmitted through the artery (column 8, line 42 through column 9, line 56; column 5,

lines 50-59); ii) processing the velocity displacement data to generate arterial displacement data using a data analyzing means (column 12, lines 30-60); (iii) adjusting the arterial displacement data using blood pressure data (column 12, lines 30-35; column 13, lines 33-55); and (iv) analyzing the adjusted arterial displacement data to characterize vascular function (column 13, lines 14-23). See Figure 1.

However, Sunagawa et al. do not specifically disclose that the velocity displacement data is acquired from arterial color tissue Doppler imaging, nor that the analysis of the ultrasound signals and adjustment of the arterial displacement data using the blood pressure data is done by software. Lin discloses a system for performing ultrasonic imaging of the absolute mean velocity and direction of flow or motion in complex media, including soft biological tissue (column 3, lines 13-15). The device performs ultrasonic color Doppler imaging of the absolute velocity and direction of fluid flow or tissue motion in complex media (column 3, lines 23-26). Further, Lin discloses the use of signal processors that use software to implement their method (column 3, lines 32-39). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the velocity displacement data acquired from arterial color tissue Doppler imaging and have software perform the analysis and adjustment of the data. The motivation for doing so would have been to be able to visualize a spatial distribution of velocity and provide execution of the method in real-time, as taught by Lin (column 2, lines 10-17; column 3, lines 32-38).

With regards to claim 8, although Sunagawa et al. do not specifically disclose that the blood pressure data comprises diastolic and mean brachial cuff blood pressure

data, they do disclose a blood pressure meter (15) (See Figure 1). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the blood pressure data comprise diastolic and mean brachial cuff blood pressure as it is well known in the art that measurements of blood pressure typically include diastolic and mean brachial blood pressure.

7. Claims 2, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al. in view of Lin as applied to claims 1 and 6 above, and further in view of Takeda (US Patent No. 5,425,372).

With regards to claims 2 and 7, the combined references of Sunagawa et al. in view of Lin do not specifically disclose that the step of processing the velocity displacement data includes integrating velocity displacement data with respect to time. Takeda discloses a method of measuring blood pressure by monitoring and recording the arterial response (column 1, lines 19-24). They disclose that the processing of velocity displacement data includes the integration over the positive region of instantaneous acceleration with respect to time, and the quantity corresponding to the velocity change due to the wall contraction is calculated as the integration over the negative region of instantaneous acceleration with respect to time (column 9, lines 28-50). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the step of processing the velocity displacement data include integrating velocity displacement data with respect to time. The motivation for doing so would have been that this has been shown as a step in the calculation of parameters such as velocity change due to the wall calculation, as taught by Takeda (column 9, lines 28-50).

With regards to claim 9, the combined references of Sunagawa et al. in view of Lin do not specifically disclose the use of a manometer to acquire blood pressure data for measuring diastolic and mean brachial cuff blood pressure data. Takeda et al. disclose the use of a manometer to display the cuff's fluctuating pressure on a display unit in terms of a variation in the height of the mercury column of a mercury manometer (column 1, lines 16-19). They further disclose that the arterial wall stretching includes that which occurs before and after each systolic and diastolic pressure detection and between the two detections (column 1, lines 19-24). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a manometer to acquire blood pressure data. The motivation for doing so would have been to be able to display the fluctuations in pressure, as taught by Takeda (column 1, lines 19-24).

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al. in view of Lin as applied to claims 1 and 6 above, and further in view of Saji et al. (US Patent No. 5,450,568).

As discussed above, Sunagawa et al. in view of Lin meet the limitations of claim 1. However, they do not specifically disclose that the step of processing the velocity displacement data includes using a readable spreadsheet for integrating velocity displacement data with respect to time. Saji et al. disclose a method for automatically generating a numerical calculation program by a finite difference method for a physical model (column 1, lines 8-14). They further disclose that their method uses an integration table to perform their calculations (column 12, lines 25-27; column 20, lines 7-12). At the time of the invention, it would have been obvious to one of ordinary skill in

the art to use a readable spreadsheet for integrating velocity displacement data with respect to time. The motivation for doing so would have been to provide a system capable of automatically solving calculation problems, as taught by Saji et al. (column 4, lines 56-68).

9. Claims 4-5 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al. in view of Lin as applied to claims 1, 6 and 8 above, and further in view of Russel (US Patent No. 4,718,428).

The combined references of Sunagawa et al. in view of Lin do not specifically disclose that the step of adjusting the arterial displacement data includes dividing said arterial displacement data by a cuff blood pressure to obtain corrected displacement data, nor do they disclose that the step of analyzing the adjusted arterial displacement data includes generating local elasticity data by correcting the arterial displacement data by dividing said arterial displacement data by a log of the cuff blood pressure. Russel et al. disclose an apparatus and various methods for continuous non-invasive measurement of the pressure of a pulsatile fluid flowing through a flexible tube over relatively long time periods, with particular applicability to the measurement of human arterial blood pressure and other related cardiovascular parameters (column 1, lines 17-22). Russel et al. disclose that the relative magnitude of wall displacement is also directly related to the elasticity of the wall of the arterial vessel (column 4, lines 66-68). They disclose that a noninvasive pressure monitoring system that relies on relative arterial wall displacement requires that its measurements first be calibrated against pressure measurements taken by a separate reference device, such as an occlusive

cuff, which would then serve as a calibration reference for subsequent pressure values based upon arterial wall displacement measurements (column 5, lines 4-11). At the time of the invention, it would have been obvious to one of ordinary skill in the art to adjust the arterial displacement data by dividing the arterial displacement data by a cuff blood pressure to obtain corrected displacement data and generate local elasticity data by correcting the arterial displacement data by dividing the displacement data by a log of the cuff blood pressure. The motivation for doing so would have been that because arterial elasticity varies at different locations along each artery, as well as at different times for the same patient, arterial wall displacement measurements require that its measurement by calibrated against pressure measurements (i.e. cuff blood pressure or log of the cuff blood pressure), as taught by Russel et al. (column 5, lines 1-11).

10. Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al. in view of Takeda.

With regards to claim 15, as discussed above, Sunagawa et al. meet the limitations of claim 14. However, Sunagawa et al. do not specifically disclose that analyzing signals received by the ultrasonic signal receiver comprises integrating velocity displacement data with respect to time. Takeda discloses a method of measuring blood pressure by monitoring and recording the arterial response (column 1, lines 19-24). They disclose that the processing of velocity displacement data includes the integration over the positive region of instantaneous acceleration with respect to time, and the quantity corresponding to the velocity change due to the wall contraction is calculated as the integration over the negative region of instantaneous acceleration

with respect to time (column 9, lines 28-50). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the step of processing the velocity displacement data include integrating velocity displacement data with respect to time. The motivation for doing so would have been that this has been shown as a step in the calculation of parameters such as velocity change due to the wall calculation, as taught by Takeda (column 9, lines 28-50).

With regards to claim 17, Sunagawa et al. do not specifically disclose that their apparatus further comprises a manometer operatively coupled to the processor for measuring diastolic and mean brachial cuff blood pressure data. However, they do disclose a blood pressure meter (15) that is connected to the data analyzing section (8) (See Figure 1). Takeda et al. disclose the use of a manometer to display the cuff's fluctuating pressure on a display unit in terms of a variation in the height of the mercury column of a mercury manometer (column 1, lines 16-19). They further disclose that the arterial wall stretching includes that which occurs before and after each systolic and diastolic pressure detection and between the two detections (column 1, lines 19-24). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a manometer to acquire blood pressure data. The motivation for doing so would have been to be able to display the fluctuations in pressure, as taught by Takeda (column 1, lines 19-24).

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al.

As discussed above, Sunagawa et al. meet the limitations of claim 14. Although Sunagawa et al. do not specifically disclose that the blood pressure data comprises diastolic and mean brachial cuff blood pressure data, they do disclose a blood pressure meter (15) (See Figure 1). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the blood pressure data comprise diastolic and mean brachial cuff blood pressure as it is well known in the art that measurements of blood pressure typically include diastolic and mean brachial blood pressure measurements

12. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa et al. in view of Russel et al..

Sunagawa et al. do not specifically disclose that analyzing the adjusted arterial displacement data comprises generating vascular function data in the form of local elasticity data, nor that generating vascular function data comprises correcting adjusted arterial displacement data with a log of cuff blood pressure data. Russel et al. disclose an apparatus and various methods for continuous non-invasive measurement of the pressure of a pulsatile fluid flowing through a flexible tube over relatively long time periods, with particular applicability to the measurement of human arterial blood pressure and other related cardiovascular parameters (column 1, lines 17-22). Russel et al. disclose that the relative magnitude of wall displacement is also directly related to the elasticity of the wall of the arterial vessel (column 4, lines 66-68). They disclose that a noninvasive pressure monitoring system that relies on relative arterial wall displacement requires that its measurements first be calibrated against pressure

measurements taken by a separate reference device, such as an occlusive cuff, which would then serve as a calibration reference for subsequent pressure values based upon arterial wall displacement measurements (column 5, lines 4-11). At the time of the invention, it would have been obvious to one of ordinary skill in the art to generate vascular function data in the form of local elasticity data and correct the arterial displacement data by dividing the displacement data by a log of the cuff blood pressure. The motivation for doing so would have been that because arterial elasticity varies at different locations along each artery, as well as at different times for the same patient, arterial wall displacement measurements require that its measurement be calibrated against pressure measurements (i.e. cuff blood pressure or log of the cuff blood pressure), as taught by Russel et al. (column 5, lines 1-11).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER